

## REMARKS

### 1. Preliminary Remarks

#### a. Status of the Claims

Claims 1-14 are pending and under examination in this application. Applicant respectfully requests entry of the remarks made herein into the file history of the application.

### 2. Requirement for Unity of Invention

At pages 2 and 3 of the Office Action, the Examiner under 35 U.S.C. § 121 and 372 requires Applicant to elect one of the following inventions:

- I. Claims 1-7, drawn to a method of making a T cell vaccine.
- II. Claims 8 and 10-14, drawn to a T cell vaccine.
- III. Claim 9, drawn to a method of treating multiple sclerosis.

Applicant with traverse elects Group I, which is related to claims 1-7.

On pages 2 and 3 of the Office Action, the Examiner asserts that restriction is required under PCT Rules 13.1 and 13.2 because Groups I-III lack a common special technical feature that makes a contribution over WO 03/024393 (“Zhang” hereafter), Steinman (J. Exp. Med. 2001;194(5):F27-30; “Steinman” hereafter), Huseby *et al.* (J. Exp. Med. 2001;194(5):669-76; “Huseby” hereafter), and Sun *et al.* (The Journal of Immunology 2001;166:7579-87; “Sun” hereafter), and therefore allegedly do not relate to a single general inventive concept. Specifically, the Examiner asserts that Zhang teaches a T cell vaccine differing only from the instantly claimed vaccine in that it is not enriched for CD8<sup>+</sup> T cells, and that Steinman, Huseby, and Sun all teach that CD8<sup>+</sup> T cells play a pathogenic role in MS. The Examiner asserts further that it would have been obvious to enrich a MS T cell vaccine for CD8<sup>+</sup> T cells. Applicant respectfully disagrees.

Claimed inventions are unified as long as they share at least one special technical feature that makes a contribution over the prior art. *See* MPEP § 1850.I. A special technical feature makes a contribution over the prior art if it is novel and requires an inventive step. *See Id.* at § 1850.II. Applicant submits that the subject matter of the claims is neither taught nor suggested by the references cited by the Examiner, and that these references do not provide any way of arriving at the claimed subject matter.

The instant claims relate to a MS T cell vaccine made with T cells from peripheral blood mononuclear cells in which the number of CD4<sup>+</sup> T cells has been reduced prior to adding a MS associated antigen to the remaining cells. Zhang, Steinman, Huseby, and Sun do not teach or

suggest making a T cell vaccine by reducing CD4<sup>+</sup> T cells from peripheral blood mononuclear cells and then stimulating with a MS associated antigen. Furthermore, the cited references suggest that both CD4<sup>+</sup> and CD8<sup>+</sup> T cells play an important role in MS. Each of the cited references teaches that CD4<sup>+</sup> T cells are involved in MS. As a result, one of ordinary skill would have been motivated to produce a vaccine that included CD4<sup>+</sup> cells, not a vaccine where CD4<sup>+</sup> cells had been reduced. For example, Steinman discloses that CD4<sup>+</sup> T cells play a significant role in MS. *See, e.g.*, Steinman at p. F28, col. 2. Huseby teaches that both CD4<sup>+</sup> and CD8<sup>+</sup> T cells potentially mediate CNS autoimmune disease. *See, e.g.*, Huseby at p. 673, col. 2. Additionally, Sun discloses that CD4<sup>+</sup> T cells play an essential role in EAE. Sun at p. 7586, col. 1. Given the significant role CD4<sup>+</sup> T cells were believed to play in autoimmune disease, one of skill had no motivation or expectation of success for combining the cited references to arrive at an effective T cell vaccine by reducing CD4<sup>+</sup> T cells.

Therefore, Applicant submits that the claims share a technical feature of reduced CD4<sup>+</sup> T cells, which meets the unity of invention requirements of 37 C.F.R. § 1.475(b)(3). In view of the foregoing, Applicant submits that the claims of Groups I-III, which relate to claims 1-14, have unity of invention and should all be examined together.

### 3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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